

[REDACTED]

From: Ben Watson
Sent: Friday, February 15, 2013 4:29 PM
To: 'Cameron, Roger' (Roger.Cameron@KlineSpecter.com)
Cc: Bryan Aylstock (BAylstock@awkolaw.com); Tom P. Cartmell (tcartmell@wcllp.com); Renee Baggett (RBaggett@awkolaw.com); Diane K. Watkins (dwatkins@wcllp.com); Erin Copeland (External) (ecopeland@fhl-law.com); Jason Richards (JRichards@awkolaw.com); Donna Jacobs; Kari Sutherland
Subject: Re: Meet and Confer

Roger and Bryan,

Please see my responses below.

From: Cameron, Roger [mailto:Roger.Cameron@KlineSpecter.com]
Sent: Friday, February 08, 2013 1:35 PM
To: Ben Watson
Cc: Bryan Aylstock; tcartmell@wcllp.com; Balefsky, Lee; Renee Baggett; dwatkins@wcllp.com; 'ecopeland@fhl-law.com'; 'JRichards@awkolaw.com'
Subject: Meet and Confer

Ben:

On behalf of my colleagues and for myself, please accept our thanks for the opportunity to discuss with you on Monday, February 4, 2012 plaintiffs' concerns about deficiencies in the written discovery responses provided by J&J, D, Ethicon, Inc. and Ethicon, LLC in this matter. While it is apparent from our conference call that day that significant differences exist on the issues discussed, it is important to note also that progress appears to have been made.

Pending a further response from you on those issues, on which you informed us that you would need to confer with your colleagues and/or clients, please see below a truncated review of the Ethicon, Inc. response to Requests for Production of Documents, that I told you at the end of our conference that I would put together. I anticipate that this format would serve just as well, if not better, than a lengthy discussion of each RFP and that this presentation would allow you to consolidate quickly a single follow up to the conference call and this writing.

Applicable Agreements on Issues Presented:

The parties agreed to consider limiting the scope of OUS and hernia product related document production. Plaintiffs now expect to provide shortly a more limited universe of subjects of documents within these categories and that defendants will re-assess what categories of documents they consider more reasonable to produce.

[Your understanding is correct. We look forward to receiving Plaintiffs' proposed limits on ex-US and hernia documents. If Bryan Aylstock's Feb. 8 e-mail on ex-U.s documents is the proposed restriction, please confirm.]

Your clients' agreement to remove the general objections and preliminary statements from the discovery responses, we understand, applies to these RFPs.

[Your understanding on the general objections and preliminary statements is correct. We do not waive any objections by doing this, but if one of the general objections applies to a particular discovery response, we will state it specifically in response to a particular discovery request.]

Replies to Pending Objections:

Please note that these replies are not necessarily representative of all of the matters that make defendants objections in appropriate and that plaintiffs reserve the right to supplement these replies in future communications to defendants and/or the Court.

- A. In each of the RFPs in which your clients raises an objection that documents are equally available to the parties, plaintiffs call your client's attention to the procedural fact that no such objection is available in responding to an RFP. And, even if it were, your client's response does not set forth a single fact to substantiate that assertion, even though factual substantiation is required by the rules. Moreover, the facts as we know them decidedly show that equally available is not the case here. For example, note that that there are at least 150 different, relevant databases, websites and similar electronic information systems that your client utilizes (see, Response to Interrogatory No. 17) without linking productions from them to any specific production or request made and while nonetheless about 6,000,000 pages of unsourced documents, many with limited metadata.

[The production index breaks down the productions by custodian and/or source. This, along with the substantial metadata that exists, makes the extensive prior productions equally searchable to you. For example, if you want adverse event reports, you can go to the portion of the production that has been identified as the Remetrix/CHATS database. If there are particular documents that you believe that you cannot find, we would be glad to work with you to see if we can come up with a solution.]

- B. Protecting the alleged confidentiality of trade secrets and business information is another objection pervading the responses. The approved confidentiality agreement obviates the need for your client to object and withhold documents on that basis.

[We agree and will withdraw this objection as the Confidentiality Order will prevent disclosure of confidential documents.]

- C. Similarly, your client's repeated claims in response to certain RFPs that it is identifying some examples of responsive documents is not permitted under the rules of procedure. Moreover, they logically establish that your client knows the identity of all (or at least more) documents responsive to that request and that it has selected, on some undisclosed basis, only certain documents to be examples, rather than identifying or producing all documents responsive to the RFP.

[As stated above, we believe that the extensive production that has already been made is equally searchable, particularly where the custodian and/or database has been specifically given. I note below that you object to Ethicon's reference to a 12,000 page range of documents. However, those documents are intended to be responsive to AE procedures. There is nothing improper about directing you to the documents that Ethicon maintains are responsive to this request.]

- D. Please note that, while not specifically discussed during our telephone conference, your client's general objections, without specifically described support, should be considered waived and any information or documents withheld on the basis of any such objection provided.

[Since we have agreed to withdraw the general objections and provide specific objections to each discovery response, this should not continue to be an issue.]

- E. One of those non-specific objections is based on attorney work product and attorney client communication. Notably, no required log of such documents has been produced, let alone a statement that such privileged materials were actually withheld in response to any particular discovery response. Plaintiffs therefore have no way of determining whether or not answers or productions are complete and no basis on which determine whether to challenge the objection.

[We have produced a privilege log. In fact, we recently received a letter on Feb. 8 making various challenges to our privilege log.

- F. Finally, your client responds to every RFP “subject to” its objections. There is no authority for doing so and/or reserving objections in any way under the federal rules of civil procedure. Consequently, plaintiffs consider those objections to be invalidly asserted and/or waived. All documents responsive to those RFPs should be produced, regardless of the attempted reservation of objections. As this “subject to” limitation is asserted in response to each RFP, plaintiffs incorporate this paragraph into the replies to each of those objections/responses, even though this paragraph is not listed specifically in the analysis of the individual RFPs below.

[Perhaps there is a way to work through this. If we can resolve our differences on the issues that separate us, then perhaps some of the objections can be withdrawn. Hernia mesh is a good example. We must preserve this objection until we come to an agreement or we have guidance from the court. One alternative to us was to simply object and move on. We did not do that. We preserved our objections and then responded subject to those objections.]

The Individual Requests for Production:

For the sake of quick reference only, here is a table of the requests, principal objections and plaintiffs’ replies, referenced by the paragraph of the Replies section above. Note the subjects and objections and replies are not necessarily inclusive of all matters within their scope.

No.	Subject	Specified Objection (Other than Non-Specific Ones, e.g. Relevancy)	Replies
2.	Role of Each Defendant	“equally available”; examples given	A, B, C, D, E
3.	Intra-defendant, other person development contracts	“equally available”; examples given	A, B, C, D, E
4.	B/D, D, Executive Committee	“equally available”; examples given; no J&J	A, B, C, D, E; As J&J has judicially admitted to appear together with Ethicon in a single line of the verdict form in trial of Gross v. Ethicon, Inc. et al., its relations at board and executive level with Ethicon are at issue;
5.	Storage of Documents	Unreasonable burden	No facts set forth as to nature/type/age/magnitude/control/expense of retrieval
6.	Mesh document logs	“equally available”;	A, B, C, D, E
7.	Document Preservation	“equally available”; examples given	A, B, C, D, E
11.	Databases	Hernia	Refinement pending
12.	Government investigations	“equally available”; examples given	A, B, C, D, E
13.	Patent litigation	Relevancy (no statement that such documents even exist; no production)	A, B, C, D, E
14.	Documents from any litigation	Vast majority produced; “equally available”	Asked for all; A
15.	FDA documents	Hernia; “equally available”; examples given	Refinement pending; A, B, C, D, E
16.	Foreign regulatory	Hernia; “equally available”;	Refinement pending; A, B, C, D, E

	submission	examples given	
17.	Countries approved for sale	Hernia; "equally available"; examples given	Refinement pending; A, C, D, E
18.	FDA/foreign PMS	"equally available"; examples given	A, B, C, D, E
19.	483 documents	"equally available"; examples given	A, B, C, D, E
20.	Marketplace withdrawal	"equally available"; examples given	A, B, C, D, E
21.	Countries not licensing	OUS, No production	Refinement pending; B, C, D, E
22.	Countries submitted, approving	"equally available"; examples given	A, B, C, D, E
23.	Countries deferring approval	OUS, No production	Refinement pending
24.	Government standards	"equally available";	A, B, D, E; if defendants had a copy, should produce that copy
26.	Government investigations re 510(K) failure	"equally available"; examples given; see RFP 15	A,B,C, D, E
28.	Adverse events/defects	"equally available"; examples given; [Note: no hernia objection]	A, B, C, D, E
29.	Efficacy	"equally available"; examples given	Refinement pending; A, B, C, D, E
30.	Preclinical, clinical	"equally available"; examples given	A, B, C, D, E
31.	Study reports	"equally available"; examples given	A, B, C, D, E
32.	Study protocol	"equally available"; examples given	A, B, C, D, E
33.	Proposed safety studies	"equally available"; examples given	A, B, C, D, E
34.	AE procedures	"equally available"; examples given	A, B, C, D, E [Excluding custodial productions references, just the single bates number production referral is >12,000 pages]
36.	Manufacturing	"equally available"; examples given	A, B, C, D, E
37.	Design Documents	"equally available"; examples given	A, B, c, D, E
38.	Manufacturing SOPs	"equally available"; examples given	A, B, C, D, E
41.	User complaints	"equally available"; see No. 35	A, B, C, D, E [not all complaints are included in database]
42.	Hospital complaints	"equally available"; see No. 35	A, B, C, D, E [not all complaints are included in database]
43.	Internal communications re AE	"equally available"; examples given	A, B, C, D, E
47.	Medical literature	"equally available";	A, B, C, D, E
48.	Bibliographies	Definition unclear; no hernia	Refinement pending; bibliographies of literature is intended meaning
49.	Communications with	"equally available"; examples	A, B, C, D, E

	journals	given	
50.	Documents re literature	"equally available"; examples given	A, B, C, D, E
51.	Epidemiology studies	"equally available"; examples given	A, B, C, D, E
52.	Data from published studies	"equally available";	A, B, C, D, E
53.	Data from unpublished or discontinued studies	"equally available"; OUS	Refinement pending; A, B, D, E
54.	Registries	"equally available"; OUS	Refinement pending; A, B, C, D, E
55.	Pre-clinical Testing	"equally available"; OUS	Refinement pending; A, B, C, D, E
56.	Pre-clinical and clinical investigator notebook	"equally available; OUS	Refinement pending; A, B, C, D, E
57.	Internal communications re safety	"equally available"	A, B, C, D, E
58.	SOPs for PMS	"equally available"; examples given	A, B, C, D, E
59.	SOPs for Pre-clinical and Clinical Trials	"equally available"; examples given; OUS	Refinement pending; A, B, C, D, E
60.	SOPs for recording and reporting AEs internally and to regulators	"equally available"; examples given; OUS	Refinement pending; A, B, C, E
61.	Documents re providing information to consumers, HCPs	"equally available"; examples given;	A, B, C, D, E
62.	Meetings with doctors and investigators re pre-clinical and clinical trials	"equally available"; examples given; beyond ESI	A, B, C, D, E; ESI does not limit scope of all discoverable materials
63.	Pre-clinical and clinical documents from doctors and investigators NOT provided to FDA	"equally available"	A, B, D
64.	Retention of 3 rd party safety, efficacy analyses	"equally available"; examples given;	A, B, C, D, E
65.	Compensation for 3 rd party mesh work, including literature	"equally available"; examples given; OUS	Refinement pending; A, B, C, D, E
66.	Groups tasked with addressing questions on safety and efficacy	"equally available";	A, B, D, E
67.	Global Safety Board	"equally available"; hernia; OUS	Refinement pending; A, B, D, E
68.	Manufacturing processes	"equally available"; examples given;	A, B, C, D, E
69.	Changes to manufacturing process considered but not adopted	"equally available"	A, B, C, D, E
70.	Design documents	Duplicative RFP 37	Withdrawn
71.	Design changes	Duplicative RFP 37	If defendants agree to consider proposed and/or considered design changes within the scope of RFP 37 and produce such documents in response

			to that RFP, Withdrawn
72.	Mesh Product safety comparisons to other PFR, SUI products	Duplicative RFP 4, 28, 30, 33, 47, 57, 61	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn
73.	Mesh Product efficacy comparisons to other PFR, SUI products	Duplicative RFP 4, 28, 29, 30, 33, 47, 57, 61	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn
74.	Safety and efficacy comparisons to own and others' products	Duplicative RFP 72, 73	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn
75.	Evaluations of safety	Duplicative of RFP 29, 30 33	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn
76.	Agreements re testing, R&D, evaluation	Duplicative of 3, 27, 65	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn
77.	QA/QC policies and procedures	"equally available"; examples given;	A, B, C, D, E
78.	Inserts, IFUs	"equally available" examples given; hernia	Refinement pending; A, B, C, D, E
79.	Approved Core Data Sheets	No definition - CDS; hernia	Refinement pending; See CFR for definition
80.	Dear Doctor/HCP letters	"equally available"; examples given	A, B, C, D, E
81.	Consumer info sheets/brochures	"equally available"; examples given	A, B, C, D, E
82.	Detail aids, doctor promotional documents	"equally available"; examples given; OUS	Refinement pending; A, B, C, D, E
83.	Promotionals left with HCPs	Duplicative RFP 81, 82	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn
84.	Doctor training materials	"equally available"; examples given	A, B, C, D, E
85.	Logs of sales materials	Duplicative RFP 81-84	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn;
86.	Copy Review Documents	"equally available"; examples given;	A, B, C, D, E
87.	Marketing and Launch plans	"equally available"; examples given;	A, B, C, D, E
88.	TV Ads	None	???
89.	Radio Ads	"equally available"; examples given	A, B, C, D, E
90.	Documents identifying ad/PR firms	"equally available"; examples given	A, B, C, D, E

91.	Documents memorializing broadcast of TV/radio ad	"equally available"	A, B, D, E
92.	Direct to Consumer campaigns	"equally available"; examples given	A, B, C, D, E
93.	Print advertisements	Duplicative RFP 91, 92	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn;
94.	Event advertisements	"equally available"	A, B, D, E
95.	Focus groups/surveys	"equally available"; examples given	A, B, C, D, E
96.	Website	"equally available"; examples given; non-ESI;	A, B, C, D, E; ESI does not limit scope of all discoverable materials
97.	Internet advertisements	"equally available"; examples given; non-ESI;	A, B, C, D, E; ESI does not limit scope of all discoverable materials
98.	Identification of Sales Reps	"equally available"; examples given;	A, B, C, D
99.	Training documents	"equally available"; examples given	A, B, C, D
100.	Training videos	Duplicative RFP 99	If defendants agree to consider documents responsive to this RFP to be within scope of that RFP and produce such documents in response to that RFP, Withdrawn;
101.	Audio and Video files for Training	Duplication RFP 99	If defendants agree to consider documents responsive to this RFP to be within scope of that RFP and produce such documents in response to that RFP, Withdrawn;
102.	Audio communications to sales force	"equally available"; examples given	A, B, C, D
103.	Emails, writings to sales forces	"equally available"; examples given	A, B, C, D, E
104.	Sales call, field notes	Will discuss data production from "Goldmine"	B, D, E Without waiving their rights and as a predicate to such discussions, Plaintiffs require a writing describing the scope and time period of the data
105.	HCP product orders	No substantive response	B, D, E
106.	Sales rep details re HCP contacts	Duplicative RFP 104	If defendants agree to consider documents responsive to this RFP to be with the scope of that RFP and produce such documents in response to that RFP, Withdrawn
107.	US regulatory comment on promotions	Duplicative RFP 12, 15, 18, 19, 21-26	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn;
108.	Procedures for sales reps to record HCP visit details	"equally available"; examples given	A, B, C, D, E
109.	Training sales representative	Duplicative RFP 99, 103-106, 108	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn;
110.	Sales representative	"equally available"; examples	A, B, C, D, E

	compensation	given	
111.	Identification of thought leaders	No substantive response	B, D, E
112.	Market share, sales US	No substantive response	B, D, E
113.	Market share, sales OUS	OUS; no substantive response	Refinement pending; B, D, E
114.	Labeling SOPs	"equally available"	A, B, D, E
115.	Dear HCP SOPs	"equally available"	A, B, D, E
116.	SOPs for Inserts	"equally available"	A, B, D, E
117.	Information on Use, Contraindications, Complications for HCPs	"equally available"	A, B, D, E
118.	Documents re Marketing	Duplicative RFP 87, 90, 92	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn;
119.	Mesh Revenue US	No substantive responsive	B, D, E
120.	Mesh Profits US	No substantive responsive	B, D, E
121.	Media reports	"Equally available"	A; availability of such reports is not equal public sources, as the identities of most such sources are unknown to plaintiffs
122.	Web marketing	Duplicative RFP 96, 97	If defendants agree to consider documents responsive to this RFP to be within scope of those RFPs and produce such documents in response to those RFPs, Withdrawn;
123.	Facebook marketing	Duplicative RFP 122	If defendants agree to consider documents responsive to this RFP to be within scope of that RFP and produce such documents in response to that RFP, Withdrawn;
124.	Chatroom marketing	Duplicative RFP 122	If defendants agree to consider documents responsive to this RFP to be within scope of that RFP and produce such documents in response to that RFP, Withdrawn;

[We incorporate our responses to A-E above to the RFPs identified in this chart. Where we have objected based on duplication, we will produce documents for these requests pursuant to the original, non-duplicative request subject to any objections in the original request.]

With our agreements and disagreements now spelled out and ripe for resolution, your clients' prompt reply, in conjunction with their promised replies to the matters we discussed on Monday, would be appreciated. It is our intention to move these issues forward quickly through the meet and confer process or motion practice, if necessary.

Yours truly,

Roger P. Cameron